

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CYTYC CORPORATION, )  
Plaintiff, )  
v. ) CIVIL ACTION NO.  
Defendant. ) 03-11142-DPW  
[Lead Case]  
TRIPATH IMAGING, INC., )  
Defendant. )

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TRIPATH IMAGING, INC., )  
Plaintiff, ) CIVIL ACTION NO.  
v. ) 03-12630-DPW  
CYTYC CORPORATION, )  
Defendant. )

MEMORANDUM AND ORDER

November 28, 2005

Plaintiff Cytac Corporation ("Cytac") commenced a declaratory judgment action against defendant TriPath Imaging, Inc. ("TriPath") in this court in June 2003, seeking a finding of invalidity and non-infringement with respect to six TriPath patents.<sup>1</sup> That action, (No. 03-11142), which has been designated the lead case, was later consolidated in this litigation with an infringement action TriPath had initially filed against Cytac in North Carolina, which was transferred to this court (No. 03-12630).

On the ultimate questions, TriPath contends that Cytac's

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<sup>1</sup> Cytac subsequently dropped its claims relating to two of the six patents initially challenged.

ThinPrep Imaging System ("ThinPrep") and the use thereof infringes upon claims of four TriPath patents regarding the automated or semi-automated screening of biological samples, primarily Pap smears of cervical cell specimens. Specifically, TriPath alleges infringement of United States Patent Nos. 6,327,377 (the "'377 patent"), 5,257,182 (the "'182 patent"), 5,715,327 (the "'327 patent"), and 5,793,969 (the "'969 patent"). Cytac argues that ThinPrep does not infringe the patents and also that the patents are invalid as anticipated by prior art.

Before taking up the ultimate questions of infringement and invalidity, however, threshold disputes between the parties regarding the construction of various claim terms must be resolved. See Watts v. XL Systems, Inc., 232 F.3d 877, 880 (2000) ("The determination of infringement is a two-step process. First, this court construes the claims and, second, we compare the properly construed claims to the accused device."). In this Memorandum, I construe the claim terms of each patent in turn.<sup>2</sup>

#### I. CLAIM CONSTRUCTION

Claim construction is a question of law, to be determined by a judge. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996). This is because "there is sufficient reason to treat construction of terms of art like many other responsibilities

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<sup>2</sup> Attached as an Appendix to this Memorandum is a summary of the claim constructions of those terms--both disputed and agreed upon--that were the subject of the three-day Markman hearing in this matter.

that we cede to a judge in the normal course of trial, notwithstanding its evidentiary underpinnings." *Id.* at 390. In Phillips v. AWH Corporation, the Federal Circuit recently set forth comprehensive guidelines for claim construction. 415 F.3d 1303 (Fed. Cir. 2005). Phillips reaffirms the "'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The claims are "of primary importance, in the effort to ascertain precisely what it is that is patented." *Id.* (quoting Merrill v. Yeomans, 94 U.S. 568, 570 (1876)).

Because the patentee is required to define precisely his or her invention, to "construe [a claim] in a manner different from the plain import of its terms" would be "unjust to the public, as well as an evasion of the law." *Id.* (quoting White v. Dunbar, 119 U.S. 47, 52 (1886)). Thus, claim terms "are generally given their ordinary and customary meaning." *Id.* (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (1996)). However, the ordinary and customary meaning of a claim is not that of a layperson, but "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention."<sup>3</sup> *Id.* at 1313. Patents are typically addressed

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<sup>3</sup> For purposes of claim construction, the "time of the invention" is the effective filing date of the patent

to persons who are skilled in the field. Therefore, the understanding of a person of ordinary skill in the art provides "an objective baseline from which to begin claim interpretation." Id.

The meaning of a claim as understood by a person of ordinary skill in the art may in some cases be readily apparent to a lay judge, but often it is not. Id. at 1314. In such cases, Phillips directs district courts to a hierarchy of sources to aid in claim construction. The intrinsic record, including the claim terms themselves, the remainder of the specification, and the prosecution history, provides the best guidance as to the meaning of the claims. Id. at 1313-14. Extrinsic evidence, such as dictionaries, expert testimony, and learned treatises, may play a valuable role in claim construction. However, in a departure from the line of cases led by Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed Cir. 2002), Phillips urges caution in their use. Id. at 1319-1324.

Among the sources of intrinsic evidence, Phillips places primary importance on the claims themselves and the specification. The context in which a term is used in the asserted claim and the use of the term in other claims can be "highly instructive." Id. at 1314. The claims, "of course, do not stand alone." Id. at 1315. They "must be read in view of

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application. Phillips, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

the specification, of which they are a part." Id. (quoting Markman, 52 F.3d at 978).

Phillips reaffirmed the long-standing principle that the specification "is the single best guide to the meaning of a disputed term." Id. at 1303. In addition to its statutory role as a "full" and "exact" description of the claimed invention, the specification may reveal a patentee's distinctive definition of a term or a disavowal of claim scope. Id. at 1316. The specification is such a valuable tool that it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317. Indeed, after Phillips, it is difficult to overstate the importance of the specification in claim construction.

A court may also consult the prosecution history when construing a claim. Id. The prosecution history "can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." Id. However, the prosecution history is not a final product; it "represents an ongoing negotiation between the PTO and the applicant." Id. As such, it "often lacks the clarity of the specification" and is thus not as useful for claim construction. Id.

Although the Phillips court attaches greater value to intrinsic evidence, it approves the use of extrinsic evidence in

a limited fashion. Specifically, technical dictionaries are helpful to the extent that they assist a court to "'better understand the underlying technology' and the way in which one of skill in the art might use the claim terms." Id. at 1318 (quoting Vitronics, 90 F.3d at 1344). Expert testimony is valuable for providing background on the technology at issue, explaining how an invention works, or describing a distinctive use of a term in a particular field.

However, neither dictionaries nor expert testimony, are reliable sources for claim interpretation. Extrinsic evidence is not part of the patent, nor was it created at the same time. Id. at 1318. Extrinsic sources may not have been written for those skilled in the art and thus may not reflect the understanding of a person of ordinary skill in the art. Id. Expert testimony is generated for litigation purposes and may contain bias that is absent in the intrinsic record. Id.

The Phillips court's greatest concern with extrinsic evidence, particularly dictionaries, is that it may lead judges to construe terms in an overbroad manner:

The problem is that if the district court starts with the broad dictionary definition in every case and fails to fully appreciate how the specification implicitly limits that definition, the error will systematically cause the construction of the claim to be unduly expansive.

Id. at 1321. Because dictionaries provide a broad array of definitions, "heavy reliance on the dictionary divorced from the

intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract." Id. The Texas Digital line of cases adopted this "dictionary down" approach, thereby reducing the role of the specification to a mere "check on the dictionary meaning of a claim term." Id. at 1320. In contrast, Phillips articulates a "claims up" approach, instructing courts to focus "at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down." Id. at 1321.

In addition to the problem of overbroad construction, Phillips warns of "the danger of reading limitations from the specification into the claim." Id. at 1323. The purpose of the specification is to enable one skilled in the art to make and use the invention. Id. at 1333. Specific embodiments of the invention described for teaching purposes should not be imported into the claim as a limitation. Id. The distinction between proper claim construction and improper limitation turns on "whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature." Id. at 1323.

Ultimately, there is no "magic formula" for conducting claim construction. Id. at 1324. The key lies in giving appropriate weight to each "source in light of the statutes and policies that inform patent law." Id. Accordingly, the claims and the

specification are most significant, followed by prosecution history, and finally by extrinsic sources. Id. With these principles in mind, I turn now to consideration of the disputed claim terms in the '377, '182, '327, and '969 patents respectively.

## II. DISPUTED TERMS

### A. '377 patent (Rutenberg)

The '377 patent describes a semi-automated screening system and method for classifying cytological specimens. In the preferred embodiment, the screening device consists of an automated microscope, a camera, a barcode reader, a slide marker, and a computer processing system. '377 patent at col. 4, ll. 44-47. This screening device preferably performs two classifications designed to identify potentially malignant cells. A human then conducts a third review. Id. at col. 5, ll. 5-7.

The primary classifier is a low resolution scan in which the image processor screens out objects that are too small, too dark, or too light to be malignant. Id. at col. 11, ll. 13-15. The secondary classifier is a high resolution scan conducted by a neurocomputer. Id. at col. 11, ll. 24-25. It classifies the remaining cells by assigning them a number from 0.1, for benign cells, to 0.9, for malignant cells. Id. at col. 16, ll. 57 - col. 17, l. 2. The computer then presents the sixty-four most suspect cells to a cytotechnologist for final classification.

Id. at col. 17, ll. 14-15.

The two terms at issue, "classifying the specimen" and "images of objects", appear in claims 11, 16, and 18.

Claim 11 provides:

A method for providing interactive review of objects in a specimen indicative of the highest likelihood of abnormality in the specimen; and

- a) obtaining the specimen; and
- b) classifying the specimen to determine the likelihood that individual objects in the specimen have attributes of cell abnormality justifying further evaluation, said classifying including
  - i) assigning individual objects in the specimen a value according to the likelihood that an object has attributes of cell abnormality, and
  - ii) selecting location coordinates of one or more of the objects to provide for viewing and further classification by a human.

'377 patent at col. 21, ll. 39-53.

Claim 16 provides:

A method of providing location-guided scanning of a specimen for objects in the specimen having a likelihood of cell abnormality, comprising the steps of:

- a) obtaining the specimen; and
- b) classifying the specimen to determine the likelihood that individual objects in the specimen have attributes of cell abnormality justifying further evaluation, said classifying including
  - i) ranking objects in the specimen in an order according to the likelihood that an object has attributes of cell abnormality, and
  - ii) identifying locations of one or more of the objects to provide viewing and further classification by a human.

Id. at col. 22, ll. 8-20.

Claim 18 provides:

The method of claim 16, further comprising the step of presenting images of objects to a human corresponding to one or more of the identified locations.

Id. at col. 22, ll. 8-20.

1. "Classifying the specimen" (claims 11 and 16)

The parties agree as to plain meanings of "classifying" and "specimen." The dispute focuses on whether "classifying" includes the steps enumerated in claims 11(b)(i) and (ii) and 16(b)(i) and (ii). Specifically, the parties disagree on whether these steps include tertiary classification conducted by a human.

Tripath argues that the language "said classifying including" at the end of claims 11(b) and 16(b) necessarily incorporates each of the steps in claims 11(b)(i) and (ii) and 16(b)(i) and (ii), respectively. Steps 11(b)(ii) and 16(b)(ii) are actions that provide for "viewing and further classification by a human." Thus, classification is not complete until a person has reviewed the suspect specimens. In contrast, Cytac contends that the device itself classifies the specimen so that further review by a human could take place, if needed. The machine, therefore, completes the classification.

A careful reading of the claim terms and the specification leads to the conclusion that the claimed invention does not include human review. Beginning with the claims themselves, the preamble to claim 11 reads "a method ... comprising the steps of...". The word "comprising" indicates a closed grouping. In

other words, the steps that follow constitute the entirety of the claim. See Manual of Patent Examining Procedure, §608.01(i)(e) (2005) ("any independent claim should contain... a preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known") (emphasis added). "Obtaining the specimen" and "classifying the specimen" are thus the only two steps claimed in claim 11.

The question remains whether "classifying the specimen" includes final, tertiary classification by a human. Claim 11(b) states that the goal of classifying the specimen is "to determine the likelihood that individual objects in the specimen have attributes of cell abnormality justifying further evaluation." (emphasis added). "Justifying further evaluation" indicates that the classification is complete when cells have been identified for further review. In contrast, a final diagnosis would not require further evaluation.

Similarly, claim 11(b)(ii) defines "classifying" as "selecting location coordinates of one or more of the objects to provide for viewing and further classification by a human." In light of the specification, the language "to provide for" means to prepare incompletely diagnosed cells for further review. Neither the specification nor the claim suggest that the secondary classifier makes or is capable of making a final diagnosis. Rather, the patent contemplates a tertiary classifier

to make the final diagnosis:

Electronic image representations of cells which are classified by the primary and secondary classifiers as being suspect are stored in the computer memory... for further (tertiary) classification by a person trained to detect the truly abnormal cells.

'377 patent at col. 8, ll. 48-53. See also id. at col. 8, ll. 57-59 ("the technician can make a final determination as to whether each of the suspect cells is truly abnormal."). Thus, claim 11 does not include the tertiary classifier, which the specification tells us, makes the final diagnosis.

TriPath argues that the '377 patent is a semi-automated method, or a method that is partly performed by humans and partly performed by machines.<sup>4</sup> To read the tertiary classification by a human out of the claims, it contends, is to disregard the semi-automatic nature of the invention. This argument fails for two reasons. First, although the specification refers repeatedly to a human as the tertiary classifier, it need not be so. The specification states that in a preferred embodiment, this classifier is a human, but it specifically reserves the possibility that it could be a machine. Id. at col. 5, ll. 5-9. Second, even if the tertiary classifier is a machine, the process still requires human involvement. For example, the automated microscope contains a coarse focus adjustment feature that can be operated manually. Id. at col. 6, ll. 53-55.

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<sup>4</sup> Cytac and TriPath agree to this definition of "semi-automated."

For the above reasons, the term "classifying the specimen" includes primary and secondary classifiers, but not a classifier, human or otherwise, that provides a final diagnosis.<sup>5</sup>

2. "Images of objects" (claim 18)

The source of disagreement is the definition of the word "image" as used in claim 18. Cytac would limit the term to "digital representations presented to the cytologist on a display monitor." TriPath argues for a broader definition: "displaying a reproduction, such as an optical counterpart, of an object produced by an optical device (as a lens or mirror) or an electronic device."

Starting once again with the terms themselves, claim 18 claims "the step of presenting images of objects to a human corresponding to one or more of the identified locations." The

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<sup>5</sup> The term "classifying the specimen" is also at issue in claim 16. Claim 16(b)(i) and (ii) are identical to claim 11, except that the word "for" is omitted in claim(b)(ii). Without the word "for", the step of "identifying locations of ... the objects" in and of itself appears to provide viewing and further classification by a human. While this literal reading tends to support the inclusion of "further classification by a human" in the definition of "classifying", it neither comports with the specification nor makes logical sense.

It is clear from the specification that identifying the location of the cells on the slides alone does not provide viewing or further classification by a human. The locations of the suspect cells are stored in the computer until they can later be inspected or examined by a human "on a video monitor." '377 patent at col. 8, ll. 48-57. Thus, it is the video monitor that provides viewing, not "identifying locations." "Identifying locations" provides for viewing and further classification in that it identifies suspect cells for tertiary review. Consequently, the same analysis of "classifying the specimen" applies to claims 11 and 16.

word "presenting" suggests that there must be a mechanism for displaying the images to the human. This narrows the definition of "image" to representations that can be displayed by the claimed mechanisms. For example, mere objects sitting on a table viewed by the naked human eye are "images" because they are viewed through the lens of the eye, but they do not fit within claim 18 because they are not "presented." Thus, TriPath's proposed definition, which would include displays viewed by the naked eye, is overly broad.

Whether a person of ordinary skill in the art, however, would understand "images" to be limited only to digital representations is a harder question. The word "image" or "images" appears one hundred forty-five times in the patent. Of those references, only ten do not imply a digital display. Seven of these ten are used to describe the historical difficulties in processing Pap smear specimens. Id. at col. 1, ll. 43-64. The three remaining terms describe the image of the specimens on the slide as viewed through the microscope lens before a camera digitizes it. Id. at col. 13, l. 34; col. 15, l. 34.

Because of these three references, TriPath urges that "image" should be construed to include slides as viewed through a microscope as well as digital images. However, claim 18 does not contemplate such a construction. Claim 18 refers to images that are to be presented to a human. The camera digitizes the image immediately after focusing. Neither the claims nor the

specification indicate that a human will view the slide through the microscope at any time before it is digitized.

Before limiting the definition of "image" to only digital representations, I must consider the possibility that a person of ordinary skill in the art in 1998, the year the patent application was filed, may have had a different understanding. In highly digitized 2005, it is easy to assume that all images would be digital, but it would be improper to construe the patent in the context of today's technology. See Phillips, 415 F.3d at 1313 ("a court construing a patent claim seeks to accord a claim the meaning it would have to a person of ordinary skill in the art at the time of the invention." (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1116 (2004))).

However, a survey of the prior art indicates that a person of ordinary skill in the art in 1998 would have understood the word "image" as used in claim 18 to refer to digital representations. The field of automated cytological screening relied extensively upon computer and digital technology for approximately forty years before the '377 patent application was filed. The first attempt at automated cytological screening occurred in the late 1950's. Nasseem Husain and Keith Watts, "Computerised Cell Scanners," Physics Bulletin 38, 198 (1988). Although largely unsuccessful, even this early system consisted of a scanner that attempted to digitize the image. Id. The

three major precursors to the '377 patent, CYBEST, Vikers' Cytology Screening Apparatus, and LEYTAS, invented in the 1960s and 1970s, respectively, each included a computer to digitize images of the specimens and a monitor to display the images as the central components of their systems. See generally, Noboru Tanaka, et. al., "CYBEST Model 4", Analytical and Quantitative Cytology and Histology, Vol. 9, No. 5 (1987); Anneke M. J. Van Driel-Kulker & Johan S. Ploem, "The Use of LEYTAS in Analytical and Quantitative Cytology," IEEE Transactions on Biomedical Engineering, Vol. BME-29, No. 2 (1982).

This history, in addition to the use of "image" in the context of computers throughout the specification and the claims themselves lead to the conclusion that a person of ordinary skill in the field in 1998 would have understood "images" to be digital representations. Following logically, "images of objects" as used in claim 18 are digital representations on a display monitor.

**B. '182 patent (Luck)**

The '182 patent entails a method of classifying cells based on their morphology and, as explained by TriPath, was developed "in order to improve the original approach set forth in the '377 [] patent to provide a more efficient or better image for the cytotechnician to evaluate." TriPath Initial Brief at 21.

The invention consists of an automated optical microscope, a

camera, a processing system with a memory, and a color monitor. '182 patent, col. 3, ll. In its preferred embodiment, the device performs three scans of the specimen slides.

First, the camera automatically focuses and captures an image of the slide at low magnification. Id. at col. 7, ll. 10-13. The image processor then digitizes the image. Id. at col. 3, ll. 55-57. In the first scan, the image processor identifies the portions of the slide that contain biological material. Id. at col. 7, ll. 14-21.

For the second scan, the camera captures at high resolution an image of the cells identified in the first scan. Id. at col. 4, ll. 6-26. The image processor locates the centers of those cells that might be malignant, and a neurocomputer assigns the cells a value indicating the likelihood of malignancy. Id.

Finally, in the high resolution rescan, the camera obtains high resolution images of the sixty-four cells identified in the second scan as the most suspect. Id. at col. 4, ll. 27-39. A summary screen displays these images for review by a cytotechnologist.

The parties debate the terms "image", "displaying" and "visual display",<sup>6</sup> and "resolution," as they appear in claims 1, 2, 3, 4, and 21. Claims 1 and 21 are independent claims. Claims

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<sup>6</sup> The parties argued the terms "displaying" and "visual display" together, and they will be addressed together in this Memorandum.

2, 3, and 4, are dependent on claim 1.

Claim 1 states:

A method of classifying objects in a cytological specimen, comprising the steps of:

- a) obtaining a first image of at least part of such cytological specimen;
- b) classifying objects in such first image on the basis of a predetermined criteria;
- c) selecting at least one object for display based on said classifying;
- d) obtaining a second image of at least part of such cytological specimen containing said at least one selected object; and
- e) displaying at least part of such second image to produce a visual display of said at least one selected object.

'182 patent, col. 14, ll. 43-56.

Claim 2 states:

The method of claim 1, wherein such first image is of a lower resolution than such second image. Id. at col. 14, ll. 57-58.

Claim 3 states:

The method of claim 1, including the step of further classifying such objects in such visual display.

Id. at col. 14, ll. 57-58.

Claim 4 states:

The method of claim 1, wherein such visual display represents plural objects.

Id. at col. 14, ll. 61-63.

Claim 21 states:

An apparatus for classifying objects in a cytological specimen, comprising:

- means for obtaining a first image of at least part of such cytological specimen;
- means for classifying objects in such first image on the basis of a predetermined criteria;

means for selecting at least one object for display based on classification performed by said means for classifying; means for obtaining a second image of such cytological specimen containing said at least one selected object; and means for displaying at least part of such second image to produce a visual display of said at least one selected object.

Id. at col. 16, ll. 26-40.

1. "Image" (claims 1, 2, 21)

The parties take positions in the construction of "image" in the '182 patent similar to those they took in construction of the '377 patent. Cytac argues for a narrow construction, "a digital representation obtained by scanning," while TriPath argues for a broad one, "a thing actually or seemingly reproducing another, such as the optical counterpart of an object produced by an optical device (a lens or mirror) or an electronic device." The debate here, however, differs from that surrounding the '377 patent in that the parties disagree only over the definition of "image" with respect to the second scan mentioned in claims 1(d) and (e), 2, and 21.

TriPath concedes that the term "first image" in claims 1(b), 2, and 21 means digital representation obtained by scanning. "First image" refers to the image captured during the initial low resolution scan of the slides described in the specification. '182 patent at col. 2, ll. 28-33. TriPath then contends that "second image", which is the image obtained by the camera during the high resolution scan, need not be a digital representation.

This distinction between the first and second images is unsubstantiated.

If the first image is digital, it follows that the second must also be digital. Claim 1(b) reads "obtaining a first image." Similarly, claim 1(d) reads "obtaining a second image." Claim terms "are normally used consistently throughout the patent" Phillips, 415 F.3d at 1314, and "should be interpreted consistently", Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998). There is no difference in the claim language here that would suggest a different meaning for the term "image." Furthermore, both the first and second image serve identical functions in the invention: to provide a representation of the specimen upon which the processor can perform a classification. If the second image were not also digital, it could not be processed by the device.

The language of the claims make clear that the "second image" must be a digital representation. The word "obtain" used in claim 1(d) means "to gain or attain possession." Webster's Third New International Dictionary 1559 (1986). This general definition finds support in the specification, which uses "obtain" and "capture" interchangeably to describe how the invention acquires an image that is capable of processing. '182 patent at col. 2, ll. 18, 20; col. 7, l. 12. The broad definition that TriPath calls for includes images, such as those produced by looking through the lens of a microscope, that are

not fixed in any tangible fashion. They exist only when viewed by the human eye. Such an image is not capable of being "obtained" or "captured", and thus cannot be classified by an image processor or a neurocomputer as called for in the claims and the specification.

TriPath argues that the images need not be obtained in digital form; that they could be captured in some other, non-electronic medium. It insists that the digital images described in the specification are merely the preferred embodiment, and should not be imported into the claims as a limitation. See Phillips, 415 F.3d at 1323. The question for a court is "whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature." Id.

A person of ordinary skill would understand that the references to digital images in the specification are not just one possible variation of the invention, but its substantive boundary. The first reference to "images" in the Detailed Description of the Invention is in the description of the camera: "a camera for obtaining electronic images from the optical microscope." '182 patent at col. 3, ll. 30-33. The specification makes a point of noting that the images obtained by the camera are electronic or digital. Id. at col. 4, ll. 14-15; col 2, ll. 25-33; col. 7, ll. 11-13. It is these electronic images that the device uses to perform the three scans. The

patent describes no other images used for any other purpose.

The Summary of the Invention, which is not a preferred embodiment, but a concise description of the entire claimed invention as conceived at the time of filing, specifically mentions digital images and repeatedly refers to images that can be processed<sup>7</sup>. Id. at col. 1, l. 65 - col. 2, l. 55. Moreover, the word "image" appears one hundred sixty-one times in the patent. Each reference either implicitly or explicitly indicates that it is a digital representation. Although it is possible that the image of the specimen viewed through the lens of the optical microscope is not digital, there is no indication in the claims or written description that the device uses those images to perform the classifications described in the claims 1 and 21.

In defense of its proposed construction, TriPath contends that the patentee in no way disavowed a broad definition of "image" during the prosecution. Cytac points out in response that the applicant failed to reply when the patent examiner found the invention to be novel because "[the prior art] fail to disclose obtaining and displaying a second image by scanning."  
'182 File History at 169, 177(emphasis added).

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<sup>7</sup> The Summary of Invention "should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed... The brief summary, if properly written to set out the exact nature, operation, and purpose of the invention, will be of material assistance in aiding ready understanding of the patent in future searches." Manual of Patent Examining Procedure, §608.01(d) (2004).

TriPath is correct that the applicant had no duty to respond to the patent examiner's unilateral reasons for allowance, and thus disavowed nothing. See Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1345 (2005) (holding that "an applicant's silence regarding statements made by the examiner during prosecution, without more, cannot amount to a 'clear and unmistakable disavowal' of claim scope.") (internal citations omitted)<sup>8</sup>. However, the patent examiner's interpretation of the term "image" is not irrelevant to claim construction: "Statements about a claim term made by an examiner during prosecution of an application may be evidence of how one of skill in the art understood the term at the time the application was filed." Id. at 1347. The patent examiner's assumption that the image is obtained by scanning further supports the conclusion that one skilled in the art would understand the term "image" as used in

<sup>8</sup> Cytyc argues that Elkay Manufacturing Co. v. Ebcō Manufacturing Co., 192 F.3d 973 (1999), applies here instead of Salazar. In Elkay, the patentee failed to respond to the Examiner's Statement of Reasons for Allowance in which the examiner explicitly approved a narrower set of claims than originally presented. Elkay then later argued for a broad claim construction that contradicted the claims as limited during prosecution. The court held that Elkay was estopped from arguing for a broad construction because he had disavowed it during prosecution. Elkay, 192 F.3d at 979.

Here, the examiner did not approve the '182 patent based on a narrow definition of "image". The examiner approved the '182 patent because it contained a second image, where the prior art contained only one. '182 File History at 177 (noting that "in the prior art of record, only one image is obtained"). Under Elkay, this record estops TriPath from arguing that the '182 patent claims only one image, but TriPath remains free to argue that the image is not necessarily obtained by scanning.

claims 1, 2, and 21 to mean digital representation.

Finally, returning to the claims themselves, the "usage of a term in one claim can often illuminate the meaning of the same term in other claims." Phillips, 415 F.3d at 1314. Although the claims at issue do not explicitly describe the images as digital, claim 11 does. Claim 11 reads, in relevant part:

A method of classifying objects in a cytological specimen; comprising the steps of:

- a) obtaining a first digital representation of at least part of such cytological specimen;
- b) storing such digital representation;
- c) performing a first filtering operation to filter out images in such representation that are the approximate size of a malignant or premalignant cell or smaller to produce a second digital representation;
- d) removing the images in such second representation from the images in such first representation to produce a third representation.

Id. at col. 15, ll. 13-24. (emphasis added). TriPath points out that the use of the term "digital representation" shows that the patent differentiates between "digital representation" and "image." Although true, this observation does not lead to the conclusion that an "image" cannot be digital. To the contrary, the language implies that the "image" must be digital. Claim 11(c), for example, states "to filter out images in such representation" (emphasis added). "Representation" logically refers to the "digital representation" in claim 11(b). Thus, the "image" must be a smaller part of the digital representation if it is to be "filtered out." The specification supports this

reading when it describes "obtaining a first digital representation" followed by a "filtering operation to filter out images in the representation." '182 patent at col. 2, ll. 27-32.

In sum, taking a "claims up" approach, the term "image" as used in claims 1, 2, and 21 refers to a digital representation.

2. "Displaying" and "visual display" (claims 1, 3, 4, 21)

TriPath contends that the terms "displaying" and "visual display" should be construed broadly to mean "spreading before the view" and "a display made available to a human observer," respectively. Cytac interprets the terms in a computer science context: "presenting information on a computer screen" and "the presentation of scanned images on a computer monitor." The disagreement here is not about the ordinary meaning of the word display, but the mechanism by which the objects are displayed. TriPath's proposed construction would not specify any particular mechanism, while Cytac would restrict the claims to only one.

Although I have construed "image" to be a digital representation, it does not necessarily follow that "display" or "visual display" must be on a computer monitor. If, for example, the patent contemplated another vehicle for presenting objects to humans, including digital images, the definition of "displaying" and "visual display" would expand to incorporate it. However, the patent appears to leave no room for a display other than on a computer monitor.

The claims themselves do not specifically mention a computer

monitor, but properly read, the intrinsic evidence suggests no alternative. Whenever the term "displaying" or "visual display" appears in the claims, it is in the context of a digital object or image. For example, claim 1(e) states "displaying at least part of such second image to produce a visual display of said at least one selected object." As discussed above, "image" refers to a digital representation. Claim 1(b) makes clear that an "object" is part of an "image" and therefore must also be digital.

Moving from the claims to the specification, the Summary of the Invention indicates only one possible mechanism for displaying digital images or objects: a monitor. The Summary describes the invention as an apparatus consisting of "a monitor for displaying at least part of the second image to produce a visual display of at least one of the objects." '182 patent at col. 2, ll. 52-54. Figure 1 is a diagram "of a cytological classification or screening device in accordance with the present invention." It shows a high resolution monitor as the mechanism for display. Figure 3, another diagram of the screening device, also shows a monitor for display.

The Detailed Description of the Invention repeatedly mentions displays on a "summary screen." See, e.g., id. at col. 4, ll. 40, 45, 46, 53, 60, 68 and col. 7, ll. 61, 62. Some of these references are, to be sure, with respect to a preferred embodiment. Keeping in mind that a court must not read a

preferred embodiment as a limitation on the claim, Phillips, 415 F.3d at 1323, the written description still points towards a monitor as the only display mechanism. The preferred embodiments provide examples of ways to configure the display on the summary screen, to arrange the images, and to identify suspect cells, but only one way to view the displays: a screen. '182 patent at col. 4, ll., 40, 45, 46, 53, 60, 68 and col. 7, ll. 61, 62. The examples make clear that the patentee contemplated a variety of uses for the displays, but never doubted that the displays would be presented on a screen or monitor.

Claim 21 uses a different form than claim 1, but yields the same definition of "displaying" and "visual display". Claim 21 reads in pertinent part, a "means for displaying at least part of such second image to produce a visual display of said at least one selected object" (emphasis added). This is a "means plus function" claim that invokes 35 U.S.C. § 112, ¶ 6:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Accordingly, the definitions of "displaying" and "visual display" are limited to the structures or their equivalents actually described in the specification. As discussed above, the specification describes no display mechanism other than a

monitor.

Therefore, the terms "displaying" and "visual display" as used in claims 1, 3, 4, and 21 refer to displays on a computer monitor or screen.

3. "Resolution" (claim 2)

Cytyc contends that "resolution" means "pixel spacing," whereas TriPath argues that this meaning is too restrictive, and the term should be construed as "the act, process, or capability of rendering distinguishable the individual parts of an object or closely adjacent optical images whether it be by magnification or pixel spacing."

At first glance, the answer appears to be straightforward. If the claims use "image", "displaying", and "visual display" in a computer science sense, then "resolution" must be construed as "pixel spacing." Indeed, Cytyc urged and TriPath appeared to concede this line of reasoning in Markman hearings held on September 6-8, 2005. However, a close reading of claim 2 and the written description leads to the conclusion that "resolution" refers to the magnification setting of the automated microscope, not pixel spacing.

Claim 2 provides: "The method of claim 1 wherein such first image is of a lower resolution than such second image." '182 patent at col. 14, ll. 57-58. The question is whether the "first image" in claim 2 is "of a lower resolution than the second

"image" because of the magnification setting of the microscope on which the specimen slide is placed or because of the microns per pixel of the digital image captured by the camera and analyzed by the processing system.

Focusing on the claim language, claim 2 reads "wherein such first image is of a lower resolution" (emphasis added). "Of" indicates that the "resolution" refers to the object of the image, not the image itself. Had the patentee chosen a different preposition, such as "at" or "in", then "resolution" would relate to the pixel spacing of the image.

The specification comports with this reading. When describing the image created by the scan, the terms "low resolution" and "high resolution" refer to the magnification setting of the microscope:

The first scan [by the microscope] of the slide is performed at a relatively low magnification, for example 50 power, and is called the low resolution scan. The second scan is performed at a higher magnification, for example 200 power, and is called the high resolution scan. The third scan is referred to as the high resolution rescan and is also performed at a high magnification.

Id. at col. 3, ll. 58-65. See also id. col. 7 ll. 1-3 ("During the low resolution scan the objective of the microscope is set, for example, at its 50 magnification power").

The specification uses "resolution" to refer to pixel spacing only when describing the digital image itself. See id.

at col. 6, ll. 44-52; col. 7, ll. 49-59. The distinction is clear in the following passage:

Once digitized by the image processor, each analysis field will be represented by a 256 by 242 matrix or array of pixels which corresponds to a resolution of approximately two microns per pixel during a low resolution scan or a high resolution scan, or a 512 by 484 array of pixels corresponding to a one micron per pixel resolution during a high resolution rescan pass.

Id. at col. 6, ll. 44-51. The resolution of the image is the same -- two microns per pixel -- for both the low resolution and the high resolution scans. The resolution of the image changes to one micron per pixel for the high resolution rescan, but the "resolution" of the rescan remains at the same 200 power magnification. Id. at col. 3, ll. 61-65 and col. 14, ll. 13.

Claim 2 includes only the first and second images. As discussed earlier, these represent the low resolution scan and the high resolution scan. Since the specification in the above quoted passage indicates that the images of these scans may be of the same resolution, "resolution" as used in claim 2 must refer to magnification.

In sum, "resolution" is not "pixel spacing", but the magnification setting of a microscope.

**C. '327 patent (Wilhelm)**

The '327 patent describes a method and apparatus for determining whether a slide is suitable for processing and has

been properly processed. '327 patent at col. 2, ll. 3-5. Specifically, the invention determines whether there were errors in specimen collection, slide preparation, slide handling, or machine processing that might lead to an inaccurate diagnosis. Id. at col. 2, ll. 8-15.

The apparatus consists of a microscope with a camera, equipment that controls movement of the slide, an image processor, a central processing system, and a workstation. Id. at col. 3, ll. 49-53. The central computer controls the microscope, camera, and image processor in order to acquire a digital image of the slide. Id. at col. 4, ll. 23-26. Then it conducts thirteen suitability tests and computes a score that indicates whether a slide has passed. Id. at col. 4, ll. 37-40. In order to produce reliable results, a slide must pass each of the tests. Id.

The parties dispute the meaning of the terms "suitably or suitable", "machine processing error flags", "accumulating", and "scan processing error flags". These terms appear in claims 1, 3, and 5.

Claim 1 provides:

A method of determining whether a slide processing system has suitably processed a biological specimen slide comprising the steps of:

- (a) processing the biological specimen slide with the slide processing system;
- (b) measuring at least one machine processing

- effectiveness parameter;
- (c) checking if the at least one machine processing effectiveness parameter has exceeded a limit; and
- (d) accumulating scan processing error flags.

Id. at col. 8, ll. 38-48.

Claim 3 provides:

The method of claim 1 wherein the scan processing error flags are generated by checking if the at least one machine processing effectiveness parameter is within a range.

Id. at col. 8, ll. 58-61.

Claim 5 provides:

A method of determining whether a slide processing system has suitably processed a biological specimen slide comprising the steps of:

- (a) processing the biological specimen slide with the slide processing system;
- (b) measuring at least one machine processing effectiveness parameter;
- (c) checking if the at least one machine processing effectiveness parameter has exceeded a limit; and
- (d) calculating at least one percentage of images acquired in focus on at least one predetermined number of tries.

Id. at col. 9, ll. 8-19.

1. "Suitably or suitable" (claims 1, 5)

The parties agree that "suitably" and "suitable" mean

"appropriate for a purpose." The dispute centers on whether the terms, which appear in the preamble of claims 1 and 5, operate as limitations on those claims. Cytyc argues that "suitably" is not a limitation; it merely describes the purpose or intended use of the invention. TriPath contends that the terms define the invention and therefore serve as substantive limitations on the claims.

A preamble "limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)). However, "a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use of the invention.'" Id. (quoting Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1977)). Ultimately, a judge determines whether a preamble is a limitation only after reviewing the entire patent "to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Id. (quoting Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)).

The word "suitably" in claims 1 and 5 is more than a mere statement of purpose; it is "essential to understand the

limitations or terms in the claim body." *Id.* The claim body lists four steps:

- (a) processing the biological specimen slide with the slide processing system;
- (b) measuring at least one machine processing effectiveness parameter;
- (c) checking if the at least one machine processing effectiveness parameter has exceeded a limit; and
- (d) accumulating scan processing error flags.

'327 patent at col. 8, ll. 37-48. These steps alone do not describe a structurally complete invention. Without the preamble to explain that the steps comprise a slide suitability test, they are no more than a series of unrelated actions. Cf., Catalina Marketing, 289 F.3d at 810 (holding that preamble language confining the use of the claimed free-standing coupon distribution terminal to consumer stores was not limiting because the location of the terminals was not a structural component of the invention).

The specification emphasizes the importance of the term "suitability" to the claims. The abstract, the summary, and the preferred embodiment repeatedly describe the invention as a "suite of suitability tests." '327 patent, Abstract, l. 2; col. 1, l. 34; col. 2, l. 17. The bulk of the specification is spent describing the claimed suitability tests and the mechanisms by which the invention performs the tests. See *id.* at col. 1, ll. 32-47; col. 2, ll. 3-48; col. 4, ll. 23-60; cols. 5-6. Indeed,

only three paragraphs of the written description do not directly describe suitability testing. See id. at col. 2, ll. 49 - col. 3.

Two of these paragraphs list related prior art that the patentee intended to incorporate by reference. The other describes Figures 1A-1C. Id. at col. 3, ll. 47 - col. 4, ll. 23. The diagrams make no mention of suitability and appear to depict a stand-alone invention, not unlike the coupon terminal in Catalina Marketing, 289 F.3d at 805. However, as discussed above, the remainder of the specification makes clear that suitability testing is not just one possible use, purpose, or intended result of the invention; it is the only use, purpose, and intended result.

Cytc argues that this case is analogous to Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc., 246 F.3d 1368 (2001). The preamble at issue in that case provided, "A method for reducing hematologic toxicity in a cancer patient undergoing [antitumor drug] treatment..." Id. at 1371. The claims that followed consisted of two steps: premedicating the patient and administering a specific dosage of the antitumor drug over three hours. Id. The Court held that the preamble language "for reducing hemotologic toxicity" did not limit the scope of the claims for two reasons. Id. at 1375. First, the steps of the three-hour infusion method were performed in the same way,

whether or not the patient actually experienced a reduction in toxicity. Id. Second, the language of the claim itself strongly suggested independence from the preamble. Id.

Bristol-Myers does not apply here. In that case, "reducing hematologic toxicity" was a result that the invention intended to, but need not, reach with each use. Id. In contrast, the steps in claims 1 and 5 of the '327 patent comprise a suitability test. Each use of the steps invariably results in a test of the suitability of a slide. The language of the claims suggest not independence, but dependence on the preamble.

TriPath contends that "suitable" is a claim limitation because the patentee relied upon it during prosecution to distinguish the prior art. See Catalina Marketing, 289 F.3d at 808 ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation."). In support, TriPath cites an Amendment dated December 18, 1995, in which the patentee stated that the prior art did not "disclose the detection of an intermediate cell or an intermediate cell nuclei for determining whether a slide preparation was suitable for processing." TriPath Ex. 8, '327 File History, Document 9, Amendment dated 12/18/95, at 6-7 (emphasis added).

TriPath misreads this statement. The very next paragraph in the Amendment makes clear that the distinction the patentee made

between his invention and the prior art turned on the use of the intermediate cell, not on the use of the invention as a suitability test.<sup>9</sup>

The patentee's failure to rely on "suitable" or "suitably" during prosecution, however, does not prevent the words from limiting claims 1 and 5. The claims themselves and the specification amply support the conclusion that "suitable" or "suitably" give "life, meaning, and vitality" to the claims, and thus should be read as limitations. See Catalina Marketing, 289 F.3d at 808.

2. "Machine processing effectiveness parameter" (claims 1, 3, 5)

TriPath urges me to construe "machine processing effectiveness parameter" according to its ordinary meaning: "a predetermined value that is an indication of whether a machine has examined the specimen properly." Cytac argues for a more

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<sup>9</sup> That paragraph provides, in relevant part: "[The prior art fails to] disclose the detection of an intermediate cell or an intermediate cell nuclei for determining whether a slide preparation result is suitable for automatic processing. [The prior art] discusses a method of eliminating the effect of overlapping cells, not dilating the intermediate cell." Tripath Ex. 8, '327 File History, Document 9, Amendment dated December 18, 1995, at 6.

The absence of the word "suitable" in the examiner's Statement of Reasons for Allowance provides further evidence that the patentee did not rely on "suitable" to distinguish his invention over the prior art. See Cytac/Callahan Decl. Ex. 35 ('327 File History, May 13, 1997, Statement of Reasons for Allowance Office Action at CO129940-43.) Not one of the reasons for allowance includes the word "suitable."

specialized construction: "a parameter, relating to a normal/abnormal diagnosis made by the machine, that describes how effectively a particular machine performs the processing." The dispute between the parties turns on whether the parameter relates to a normal/abnormal diagnosis made by the machine.

The specification indicates that "machine processing effectiveness parameter" does not relate to a normal/abnormal diagnosis. Although the entire term, "machine processing effectiveness parameter," does not appear in the specification, portions of it do. These portions shed light on the term's meaning. Consider the following excerpt from the "Background of the Invention" section of the specification:

Machine effectiveness measures, such as the percentage of requested fields of view that were focused adequately or the percentage of acquired images that had saturated pixels, are measures of how well the automated cytology system has begun to process a slide and how it proceeds to process a slide.

'327 patent at col. 1, ll. 17-22. "Effectiveness" appears to be the ability to process a slide properly. The specification uses "processing parameters" and "measures" interchangeably. See id. at col. 5, ll. 41-43. Combining these terms, a "machine processing effectiveness parameter" indicates whether the machine has examined the specimen properly. It relates not to the normal/abnormal diagnosis made by the machine, but to the reliability of that diagnosis.

This construction makes sense in the context of the entire patent. The invention at its essence is a suitability testing machine. It conducts thirteen tests and computes a score indicating how accurate a diagnosis is likely to be. The "machine processing effectiveness parameter" to which claims 1, 3, and 5 refer relates to whether a slide has been suitably processed<sup>10</sup>. It is separate from the diagnosis of normal or abnormal.

Cytyc argues that the prosecution history supports construing "machine processing effectiveness parameter" as related to a normal/abnormal diagnosis. The examiner initially rejected the claims because prior art disclosed methods of determining processing effectiveness, such as the condition of the slide and its position and movement on the microscope stage. Cytyc/Callahan Decl. Ex. 35 ('327 File History, December 18, 1995 Amendment (C0129883)). In the Amendment dated December 18, 1995, the patentee distinguished his invention by noting that the prior art did not disclose measuring and checking at least one machine processing effectiveness parameter. Id. The patentee emphasized that his invention identifies errors caused by the machine, not just the condition of the slide. Id. He further explained that "[t]he machine processing referred to in the instant

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<sup>10</sup> This follows logically from the determination that the preamble limits claims 1 and 5.

specification relates to processing the biological specimen slide to determine if the slide is normal or abnormal." Id.

Cytyc seizes upon this language to justify its proposed construction. The Amendment clearly defines machine processing as the method by which the machine arrives at a diagnosis of normal or abnormal. This, however, does not support Cytyc's definition of "machine processing effectiveness parameter." Again, the parameter is an indicator of the effectiveness of the machine processing. It relates to the ability of the machine to make a diagnosis, not the diagnosis itself.

Therefore, to be consistent with the specification and the prosecution history, the proper construction of "machine processing effectiveness parameter" is "a predetermined value that is an indication of whether a machine has examined the specimen properly."

3. "Accumulating" (claim 1)

The parties agree that the ordinary meaning of "accumulating" is gathering or amassing. The parties disagree as to whether "accumulating" refers to gathering or amassing more than one thing. TriPath argues that it can include only one thing, while Cytyc contends that it requires more than one.

The claims and the specification offer few clues as to the correct construction. "Accumulating" appears only once in the entire patent, and that is in claim 1(d). However, there is

sufficient intrinsic evidence to suggest that "accumulating" should be construed as gathering one or more things.

The preamble of claim 1 and the specification support the broader definition of "accumulating." Read together, the preamble and claim 1(d) provide: "[a] method of determining whether a slide processing system has suitably processed a biological specimen slide comprising the steps of... (d) accumulating scan processing error flags." '327 patent at col. 8, ll. 38-40.<sup>11</sup> Accumulating error flags is part of the process for determining whether the system properly processed a slide.

The invention "flag[s] the unacceptable machine condition or slide characteristic so that potentially false results are not used." Id. at col. 1, ll. 25-30. It accumulates error flags for each "unacceptable condition or slide characteristic." Id. There may be only one such condition, or there may be more. If the invention fails to "accumulate" the first error that it flags, it does not "flag the unacceptable machine condition or slide characteristic so that potentially false results are not used." Id. Thus, it defies the specification, the claims, and common sense to suggest that the invention does not "accumulate" error flags until it has identified at least two errors.

Cytyc argues that the object of the word "accumulating" is

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<sup>11</sup> As discussed earlier, the claims are not independent of the preamble.

the plural term "error flags." This weighs in favor of gathering more than one thing. Cytac also notes that claims 1(b) and (c) use the term "at least one" to refer to machine processing effectiveness parameters. If the patentee intended "accumulating" to include just one error flag, claim 1(d) could have read "accumulating at least one scan processing error flag."

Although persuasive in the abstract, these arguments do not make sense in the context of the preamble and the specification. In other words, the narrower construction does not "naturally align" with the patent's description of the invention. See Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). "Ultimately, the interpretation to be given to a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." Id. Here, the invention gathers error flags, however few there may be, to indicate whether a slide is suitable for processing. Thus, "accumulating" may encompass one or more error flags.<sup>12</sup>

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<sup>12</sup> This construction comports with the understanding of a person skilled in the art. TriPath's expert witness, Dr. Peter Bartels, testified that "accumulating" could mean gathering only one thing. Cytac/Callahan Decl. Ex. 76 (Deposition of Dr. Peter Bartels at 209). He explained that if one starts with nothing and adds one thing, this is "accumulating." Id. at 210. He noted that accumulating just one thing is an "extreme case of the definition" and may not be the common meaning, but it is how a mathematician would understand it. Id.

4. "Scan processing error flags" (claims 1, 3)

TriPath defines "scan processing error flags" as "an indication by the system (i.e. an issued flag or signal) that an error has occurred during scan processing." Cytac agrees with this definition, except that it would strike the words "or signal." Cytac argues that "scan processing error flags" are not generic signals, but specific computer software mechanisms. TriPath responds that its definition is more clear and precise because a flag is an electronic signal.

TriPath is correct that an error flag is an electronic signal. However, adding the word "signal" into the definition of "scan processing error flag" unduly expands the scope of the claims.

Beginning with the claim language, the words "scan processing" modify "error flags." This indicates that the error flags are related to the image processing process. Claim 3 explains how they are related: the "scan processing error flags are generated by checking if the at least one machine processing effectiveness parameter is within a range." '327 patent at col. 8, ll. 58-61. In other words, when the invention detects that a

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From this testimony, Cytac argues that defining accumulating as gathering just one thing is an extreme, and therefore, incorrect construction. However, the benchmark for claim construction is not the understanding of a layperson, but that of "a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313.

slide is not suitable for processing or has been processed improperly, it generates an error flag.

The specification, in the preferred embodiment, describes two types of error flags. Id. at col. 5, ll. 48-48; col. 6, ll. 53-61; Table 2. These flags are numerical values issued when errors are found at two different magnifications, 20X and 40X. Id. These two "algorithm processing error flags" are the only two of the thirteen suitability measures explicitly labelled "error flags." Id.

However, this alone does not support a narrow reading of "scan processing error flags." The Abstract refers to other types of flags: magnification error flags, staining flags, main optical density flags. Id. at Abstract. The specification also appears to use "flag", "measure", and "test" as related and sometimes interchangeable nouns. See, e.g., id. at col. 1, ll. 35-37 ("The [suitability] tests include machine processing error flags, staining measures..."); col. 5, ll. 58-59 ("Table 2[, which lists the 20X and 40X error flags mentioned above,] provides a short description of each measure used to test slide suitability").

These flags, measures, and tests mentioned in the written description are indeed signals. However, they are particular types of signals used for a particular purpose. A computer conducts the image processing and slide suitability scoring, so

the signals must be electronic. The thirteen suitability tests are, at their essence, computer software mechanisms that indicate when an error has been detected. To construe "scan processing error flags" to include any other type of signal, is inconsistent with the specification and the claims.

**D. '969 patent (Kamentsky)**

The '969 patent describes a network system for review and analysis of computer encoded microscope slides and specimens. '969 patent at col. 5, ll. 10-14. During the initial examination of a slide, a microscope equipped with an encoder device encodes information, such as parts of the slide that have been viewed, events of interest for diagnosis, and -- for quality control purposes -- the manner in which the initial slide examination was conducted. Id. at col. 5, ll. 10-19. This information is stored on a networked file server. Id. at col 5, ll. 14-17.

Users can access this information at a series of microscope stations linked by a modem or local access network ("LAN"). Id. at col. 5, ll. 19-22. In addition, the invention allows users to access images from an online library and patient information while simultaneously viewing a slide, either directly through a microscope or as a stored digital image. Id. at col. 5, ll. 19-34.

The parties dispute the meanings of the following four terms

as they appear in claims 16, 17, and 21 of the '969 patent: "microscope stations", "means for computing", "means for automatically recording location information of interest", and "cell analysis information".

Claim 16 provides:

A network of interconnected microscope stations comprising:

- (a) a means for operatively linking microscope stations; and
- (b) a plurality of microscope stations connected to the means for operatively linking microscope stations, wherein a microscope of the plurality of microscope stations includes:
  - (i) a moveable slide stage for mounting a specimen slide having a specimen;
  - (ii) a means for computing wherein information relating to the specimen slide being examined by the microscope is stored by the means for computing and is made accessible to other microscopes; and
  - (iii) means for automatically recording location information of interest of the movable slide stage during a microscope examination, wherein the automatically recorded location information of interest represents microscope viewing locations on the specimen slide that are locations of interest.

'969 patent at col. 13, l. 47 - col. 14, l. 4.

Claim 17 provides:

The network of claim 16, wherein each microscope station in the network of the interconnected microscope stations further comprises a terminal for a data base having information relevant to appropriate examination of the slide specimen.

Id. at col. 14, ll. 5-9.

Claim 21 provides:

The network of claim 16, wherein the network further includes at least one cell analysis instrument and wherein at least one interconnected microscope station of the network of interconnected microscope stations further comprises a terminal for receipt of analysis from the cell analysis instrument.

Id. at col. 14, ll. 29-34.

1. "Microscope station" (claims 16, 17, 21)

Cytyc argues that the term "microscope station" should be construed as "equipment, not including a cell analysis instrument, at which a human operator performs microscope analyses." Tripath objects to the exclusion of cell analysis instruments and the requirement of a human operator. It proposes a broader definition: "a place equipped with a microscope." The claims and the specification support the narrower definition.

Claim 16(b) describes three elements that each microscope within a "microscope station" must include: a movable slide stage, a means for computing that stores and shares information about the slide being examined, and a means for automatically recording location information of interest of the slide stage during slide examination. Claim 16 by itself appears to define "microscope station" broadly as any location equipped with a microscope that satisfies the three requirements. However, four

dependent claims suggest a narrower meaning.

Claim 17 adds to the microscope station a terminal for a database having information relevant to the appropriate examination of the slide specimen. Claim 22 adds a means for recording time information, such as how long a previous user spent viewing a particular location of interest on the slide. These claims indicate that a "microscope station" is a place where a user can store and retrieve information about slides for use in diagnosis.

Claims 21 and 24 further narrow the definition of "microscope station" by distinguishing a "cell analysis instrument". Claim 21 states that the network "includes at least one cell analysis instrument and that at least one microscope station "comprises a terminal for receipt of analysis from the cell analysis instrument." Claim 24 states that separate microscope stations are "linked to a cell analysis instrument" and "analysis data from the cell analysis instrument and results of the microscope examination are simultaneously available at the separate microscope stations for review thereof." These two claims make clear that the cell analysis instrument is a specialized machine for producing analytical data. In contrast, the "microscope station" receives the data from the cell analysis instrument and other sources. Its purpose is to allow users to access the data.

The specification supports this distinction between a "microscope station" and a "cell analysis instrument." The specification repeatedly refers to "microscope stations" as places where end users access data. For example, the Detailed Description of the Invention states:

The network reviewing method comprises the step of causing the computer storage means to be independently accessible by at least two separate microscope stations in a network, each of the stations comprising a microscope and computer means, with each of the microscope stations being separately individually linked to at least one computer means capable of recalling the stored movements and location information from the... microscope used in the original examination.

Id. at col. 3, ll. 13-23. Another passage reads:

recalling, at one or more of said microscope stations from said computer storage means, a computer generated image of a slide..., onto the viewing means of the respective microscope station for review.

Id. at col. 3, l.65 - col. 4, l. 1.

Beginning at column 8, line 10, the specification describes in detail how a pathologist uses the "microscope station" in practice. Id. at col. 8, l. 10 - col 9, l. 24. The pathologist interacts with the "microscope station" by placing the slide on the stage, finding locations of interest, viewing data on a screen, and printing reports. Id. These examples show that a "microscope station" is a place where different types of information is gathered, stored, and viewed. It follows that the

"microscope stations" must have some means for data storage, sharing, and access by a human.

The description of "cell analysis instrument" is quite different. The specification provides examples of four types of instruments: hematology analyzers, PAP smear analyzers, image analyzers, and laser scanning cytometers. Id. at col. 9, ll. 25-27.<sup>13</sup> These instruments scan slides and process the data from these slides. Id. at col. 9, ll. 27-30. They then isolate, locate, and characterize cells based on the scan data. Id. Importantly for purposes of claim construction, the specification states that "[o]ne or more of the instruments can be interfaced with at least one of the microscope stations on the network in accordance with the present invention." Id. at col. 9, ll. 30-33. This last sentence makes clear that a cell analysis instrument is not part of a "microscope station." It can be linked to a "microscope station" so that its data can be accessed there, but it is a separate apparatus.

Figure 1 illustrates these differences between "microscope station" and "cell analysis instrument" in a preferred embodiment. The Cytology Lab Pathfinders and Anatomic Pathology Pathfinders, represented by the number one, consist of a microscope equipped with stage position encoders, a

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<sup>13</sup> Claims 25-28 specifically claim each of these four types of instruments.

microprocessor, a display screen and a keyboard. Id. at col. 6, ll. 54-58. These are "microscope stations." Id. The Pathfinder DS System, numbers four and eight, has similar components, and is also a "microscope station." The Laser Scanning Cytometer, which is a type of cell analysis instrument, is shown as number five. Id. at col. 9, ll. 36-37. It is depicted as a separate entity, with different components than the "microscope stations." Id. at col. 9, ll. 37-39.

TriPath contends that Figure 1 depicts four types of "microscope stations": Cytology Lab Pathfinders (number one), Anatomic Pathology Pathfinder (number one), Pathfinder DS System (numbers four and eight) and the Laser Scanning Cytometer (number five). It contends that these "stations" meet the requirements of claim 16 because each includes a microscope, some sort of microprocessor or personal computer, and a microscope staged encoder.

However, TriPath fails to recognize that the requirements of claim 16(b) refer only to the microscope component of a "microscope station." Claim 16(b) leaves open the possibility that a "microscope station" has other features.<sup>14</sup> As I

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<sup>14</sup> The preamble of claim 16 (b) provides: "A network of interconnected microscope stations comprising..." From this language, it is not clear whether "comprising" refers to the "network" or the "microscope stations." However, claims 16(a) and (b) refer to the connections between microscope stations, suggesting that claim 16 read as a whole describes the elements comprising the network, not the microscope stations.

explained above, the specification and the other claims define these other features in such a way that a "microscope station" is a place, separate from a cell analysis instrument, where a human conducts cell analysis and review.

TriPath also argues for a broader construction on the grounds that independent claims must be construed independently of and irrespective of dependent claims which specify a specific structure. It relies on Laitram Corp. v. Rexnord, Inc., 939 F.2d 1553, 1558 (Fed. Cir. 1991), for this proposition. However, Laitram does not apply to the present situation.

In Laitram, independent claim 21 contained a means-plus-function claim relating to a "means for joining" ends of a conveyer belt. Id. at 1534-35. Dependent claim 24 specifically required a cross-member as a means for joining the ends of the belt. Id. at 1538. Laitram argued that claim 21 could not also require a cross-member because that interpretation would violate the prohibition against reading limitations from a dependent claim into the independent claim and would frustrate the doctrine of claim differentiation. Id.

The Federal Circuit rejected both of these arguments. Id. It held that the interpretation of "means for joining" as requiring a cross-member was proper because it derived from the specification, not the dependent claims. Id. It also found that claim differentiation was a judicially developed presumption that

did not override § 112, ¶ 6, the statute authorizing means-plus-function claims. Id.

In this case, unlike Laitram, the term "microscope station" itself is not a means-plus-function claim governed by §112, ¶ 6. Claim 16(b) (ii) and (iii) are means-plus-function claims describing two elements of the microscopes in a "microscope station." I do not read claims 17, 21, 22 and 24 as enumerating the means required to complete the functions in claims 16(b) (ii) and (iii) or as limiting claim 16 to the structures in the dependent claims. Rather, I look at the dependent claims to shed light on the meaning of a term that appears in the independent claim and three of the four dependent claims. See Phillips, 415 F.3d 1314 ("Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.").

Finally, TriPath claims that Cytyc's proposed construction is incorrect because it would invalidate the preferred embodiment. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, (Fed. Cir. 1996) (holding that an interpretation that invalidates the preferred embodiment is "rarely, if ever, correct and would require highly persuasive evidentiary support"). This is simply not the case. Figure 1 represents the preferred embodiment. '969 patent at col. 6, ll. 54-55. As discussed earlier, the Cytology Lab Pathfinders and the Anatomic Pathology

Pathfinders are "microscope stations" that contain the movable slide stage, means for computing, and means for automatically recording required by claim 16. Id. at col. 6, 56-58. The Pathfinder DS System, depicted as numbers four and eight, is also a "microscope station" according to claim 16. Id. col. 7, 11. 50-55; col 8, 11. 28-29, 59-61. The Laser Scanning Cytometer is a "cell analysis instrument" that meets the requirements of claims 21, 24 and 28. Therefore, the preferred embodiment falls within the claims and is presumably valid.

In sum, the specification and claims support a narrow reading of "microscope station." Thus, I construe "microscope station" to be equipment, not including a cell analysis instrument, at which a human operator performs analysis.

2. "Cell analysis instrument" (claim 21)

Cytec contends that a "cell analysis instrument" is "a device, not including a microscope station, that performs measurements or analysis of at least one cell feature on a specimen preparation, such as a specimen slide." TriPath's proposed definition is, "an instrument that automatically conducts a detailed assessment or examination of one or more cells to determine its nature or essential features." The disagreement centers on three issues. First, whether a cell analysis instrument is or includes a microscope station; second, whether it performs "measurements"; and third, whether it

conducts assessments automatically or requires human input.

The above discussion of "microscope station" resolves the first issue. A "cell analysis instrument" is not, and does not include, a microscope station. Therefore, the remainder of this section will focus on the second and third issues.

The claims provide little guidance as to whether the cell analysis instrument performs measurements. Claim 21 states that the cell analysis instrument produces "analysis", but does not provide any further details. '969 patent at col. 14, l. 33. Similarly, claim 24 states that the cell analysis instrument produces "analysis data." Id. at col. 14, l. 49.

The specification is more helpful. As mentioned above, the specification lists examples of four types of cell analysis instruments. Id. at col. 9, ll. 25-30. The only type that it describes in detail is a particular brand of laser scanning cytometer, the CompuCyte LSC™ ("LSC"). Id. at col. 9, l. 27. The description states that the

LSC can scan slides stained with fluorescent dyes to measure the constituents and morphology of cells on the slide and generate a computer database file containing a set of constituent values, morphology values and slide position values of every cell found by it on the slide.

Id. at col. 9, ll. 39-44 (emphasis added). This passage indicates that the patentee intended a cell analysis instrument to conduct measurements.

Moreover, the sentence introducing the four types of cell analysis instruments begins, "There are at least four types of instruments." Id. at col. 9, ll. 35 (emphasis added). The words "at least" make clear that the four listed types are examples; they are not the outer limits of the claims. The patentee does not define any specific method of analysis that the claimed "cell analysis instruments" must use. Therefore, to interpret "cell analysis instrument" as one that does not perform measurements would not only contradict the example in the preferred embodiment, but would improperly limit the scope of the claim. See Phillips, 415 F.3d at 1323 (warning against confining the claims to the embodiments in the specification when those embodiments are merely "exemplary in nature").

The claims are silent as to whether a "cell analysis instrument" operates automatically or requires human input. Again, the description of the LSC provides the only detailed example of how a cell analysis instrument functions. The LSC clearly allows some human interaction. For example, the user may move the slide to view areas of interest and annotate the positions of specific cells while the slide is on the stage. Id. at col. 9, ll. 61-62; col. 10, ll. 2-4. However, it does not appear that human interaction is required in order for the LSC to perform the analysis. Another embodiment specifically automates the movement of the microscope to locations of interest. Id. at

col. 10, ll. 6-14.

Since much of the description of the LSC is written in the passive voice, it is difficult to discern whether a machine or a human is conducting the analysis. See id. at col. 9, l. 34 - col. 10, l. 5. However, the specification is clear that the purpose of the "cell analysis instrument" is to perform "analysis", an activity that can be conducted with or without human interaction. The claims and the specification do not restrict the methods by which the "cell analysis instrument" can perform its analysis. Thus, I will not read into the claims a limitation that a "cell analysis instrument" must conduct analysis either automatically or with human input.

In sum, a "cell analysis instrument" is a device, not including a microscope station, that performs measurement or analysis of at least one cell feature on a specimen preparation, such as a specimen slide.

### 3. "Means for computing" (claim 16)

The dispute here centers on the structures that comprise the "means for computing." Cytac contends that these structures are limited to "a personal computer in the decisions support system (4) of a microscope station using Microsoft Windows, and equivalent structures." TriPath argues for a broader interpretation. It would add to Cytac's definition the personal computer in the laser scanning cytometer, the microprocessors

with stage position encoders on each Cytology Lab Pathfinder, and the LAN server.

"Means for computing" is a means-plus-function claim that invokes 35 U.S.C. §112, ¶ 6. See Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 194 F.3d 1250, 1257 (Fed. Cir. 1999) ("If the word 'means' appears in a claim element in association with a function, this court presumes that §112, ¶ 6 applies."). Section 112, ¶ 6 articulates a mandatory procedure for interpreting the meaning of a means-plus-function claim: "such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." See Al-Site Corp. v. VSI Int'l, 174 F.3d 1308, 1320 (Fed. Cir. 1999). Thus, §112, ¶ 6 "restrict[s] a functional claim element's 'broad literal language ... to those means that are 'equivalent' to the actual means shown in the patent specification.'" Id. (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997)).

The first step in construing a means-plus-function claim is to identify the function. ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1087 (Fed. Cir. 2003). Here, the function is "computing" by "a microscope of the plurality of microscope stations." '969 patent at col. 13, ll. 53-54. I have construed "microscope station" to be equipment, not including a cell analysis instrument, at which a human operator performs analysis.

The parties agree that "computing" means "to store information about the slide, which is stored by the means for computing, then made accessible to other microscopes." This definition makes sense in light of claim 16(b) (ii), which provides: "a means for computing wherein information relating to the specimen slide being examined by the microscope is stored by the means for computing and is made accessible to other microscopes." Id. at col. 13, ll. 57-60 (emphasis added).

The second step is to "examine the written description to determine the structure that corresponds to and performs that function." ACTV, 346 F.3d at 1087. The specification makes clear that "means for computing" includes the personal computer component of the Pathfinder DS System, and its equivalents. As noted in the discussion of "microscope station", the Pathfinder DS System is a microscope station. The personal computer has storage capabilities and is accessible to other microscopes via the network. '969 patent at col. 8, ll. 11, 59-62. It also uses Microsoft Windows. Id. at col. 8, l. 32. Thus, "means for computing" includes, at a minimum, Cytac's proposed construction of "a personal computer in the decisions support system (4) of a microscope station using Microsoft Windows, and equivalent structures."

It is equally clear that "means for computing" does not include the personal computer in the laser scanning cytometer.

Although the personal computer component of the LSC appears to have storage capability and can be accessed from the microscope stations, the LSC is not a microscope station. Id. at col. 9, ll. 30-35. The LSC merely generates data that can be retrieved at a microscope station.

Whether "means for computing" includes the microprocessors on each Cytology Lab Pathfinder and the LAN server is more difficult. The Cytology Lab Pathfinders are microscope stations. They contain stage position encoders, a microprocessor, a display screen, and a keyboard. Id. at col. 6, ll. 56-61. Laboratory personnel use the encoders to screen and review slides. Id. at col. 6, 58-61. The microprocessor receives data from the encoders and transmits it to the LAN server via a receiver/transmitter chip and wires. Id. at col. 6, l. 61 - col. 7, l. 4. The microprocessor can also access data from other microscope stations through the LAN server and receiver/transmitter chip, functioning as computer terminals of the network. Id. at col. 5, ll. 19-25.

The microprocessor does not appear to have any storage capability. Rather, the information gathered at the microscope stations is stored on the LAN server. Id. at col. 5, l. 14-16. The LAN server itself is not a microscope station. It is a separate personal computer that allows microscope stations on the network to share data with each other and with cell analysis

instruments, such as the LSC. Id. at col. 7, ll. 2-5, 24-27.

Because the microprocessor lacks storage ability and the LAN server is not a microscope station, a literal construction of "means for computing" would exclude both of these entities from the definition. However, a close reading of the specification shows that a more flexible construction is warranted. The microscope stations use the microprocessor and the LAN server together as a "means for computing." The LAN server stores the data and allows it to be accessed by other microscope stations. Id. at col. 5, ll. 14-16; col. 7, ll. 2-5, 24-27. The microprocessor enables data to be received, transmitted, and communicated to the end user at the microscope station. Id. at col. 5, ll. 19-25. Neither can complete the computing functions of storing and accessing data without the other. In other words, the invention "farms out" some of the microscope stations' computing functions to the LAN server.<sup>15</sup>

Thus, the "means for computing" in claim 16(b)(ii) include the personal computer in the decisions support system (4) of a microscope station using Microsoft Windows, the microprocessors on each Cytology Lab Pathfinder, the LAN server, and equivalent structures.

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<sup>15</sup> In contrast, the specification does not require that the LSC perform any computing functions for the microscope stations. The LSC supplies data that the microscope stations can access, but it does not provide data storage for the microscope stations or make the microscope stations accessible to each other.

4. "Means for automatically recording location information of interest" (claim 16)

The parties disagree on two points with respect to the construction of the term "means for automatically recording location information of interest" in claim 16(b)(iii). First, they dispute the meaning of the term "location information of interest." Second, they disagree over the structures that comprise the "means for automatically recording location information of interest."

In construing a means-plus-function claim such as this, the first step is to identify the function. ACTV, 346 F.3d at 1087. The second step is to identify the structures for performing those functions. Id. Because "location information of interest" relates to function, I will consider that term first.

Cytyc argues that "location information of interest" refers to the areas of the specimen that the reviewer has viewed through the microscope optics. TriPath contends that it means "microscope viewing locations on the slide from the initial examination of the slide (and which were automatically recorded), including the location of objects or cells of interest that are automatically recorded." The difference between the two proposed constructions is that TriPath's includes locations that are automatically recorded by a cell analysis instrument, while Cytyc's includes only those recorded by microscopes in a

microscope station.

Claim 16(b) (iii) lists one of the three requirements for "a microscope of the plurality of microscope stations." '969 patent at col. 13, ll. 53-54. It provides:

means for automatically recording location information of interest of the movable slide stage during a microscope examination, wherein the automatically recorded location information of interest represents microscope viewing locations on the specimen slide that are locations of interest.

Id. at col. 13, l. 62 - col. 14, l. 4. This language indicates that the "location information of interest" is the position on the movable slide stage of a slide that is being examined under a microscope at a microscope station.

The specification supports this reading. It describes three embodiments of the invention that automatically record location information of interest. Id. at col. 3, ll. 4-23, 40-55; col. 4, ll. 31-48. Each of these references relates explicitly to the specimen slide, either during an original examination or a subsequent examination. The invention automatically marks and records viewing area "locations of interest" of the specimen slide so that they can be reviewed at a later time by a supervisor or pathologist. Id. at col. 3, 52-54; col. 4, ll. 44-47; col. 5, ll. 19-21.

A "specimen slide" is a slide being examined at one of the microscope stations. In describing how the invention recalls the

location information of interest, the specification uses the term "specimen slide" only with reference to microscope stations.

See, e.g., id. at col. 4, ll. 4-5 ("placing the specimen slide on the movable slide stage of the microscope, at the respective microscope station"). In contrast, when referring to a specimen being examined by a cell analysis instrument, the specification uses the terms "cell" or "slide", not "specimen slide." Id. at col. 9, ll. 28, 48-50, 62-66.

Although a cell analysis instrument may also automatically record the position of slides and events of interest, id. at col. 9, l. 34-35, it is not a microscope station and does not record the positions of "specimen slides." Therefore, the term "location information of interest" as used in 16(b)(iii) refers to the areas of the specimen slide that the reviewer has viewed through the microscope optics at a microscope station.

Having resolved the function issue, I can proceed to construe the structures that comprise the "means for automatically recording location information of interest." The parties agree that the structure is a personal computer having an internal clock for automatically recording the location information of the stage at regular clock intervals, and equivalent structures. The disagreement centers on whether the personal computer may be connected to a scanning instrument, as TriPath contends, or must be part of a microscope station, as

Cytyc claims.

It follows from the construction of "location information of interest" that "means for automatically recording location information" must be part of a microscope station. The "location information of interest" is the area of the slide that the user has viewed through a microscope at a microscope station. The specification provides no means for automatically recording this information other than the computer at a microscope station. Id. at col. 4, ll. 34, 37-38. There is no suggestion that the computer component of a cell analysis instrument automatically records location information for slides on microscopes in microscope stations.

Therefore, the "means for automatically recording location information of interest" is the personal computer that is part of the microscope station having an internal clock for automatically recording the location information of the stage (and, consequently, the slide) at regular clock intervals, and equivalent structures.

/s/ Douglas P. Woodlock

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DOUGLAS P. WOODLOCK  
UNITED STATES DISTRICT JUDGE

**APPENDIX: SUMMARY OF CLAIM CONSTRUCTIONS****'377 Patent (Rutenberg)**

Term	Court construction
classifying the specimen (claims 11, 16)	classifying the specimen into one of two or more groups, including primary and secondary classifiers, but not a classifier, human or otherwise, that provides a final diagnosis
images of objects (claim 18)	one or more digital representations on a display monitor
	<b>Previously agreed-upon construction</b>
further classification (claims 11, 16)	initial classification (by the machine) must have occurred prior to the "further" classification performed by a human  Joint Submission of Agreed-Upon Claim Constructors.
attributes (claims 11, 16)	more than one attribute  Joint Submission of Agreed-Upon Claim Constructors.

ranking individual objects in the specimen in an order according to the likelihood (claim 16)	placing objects in a row, or order in such a manner that the first ranked object is the one with the greatest probability of exhibiting a particular characteristic, and the second ranked object is the object with the second greatest probability of exhibiting a particular characteristic, etc.  Joint Submission of Agreed-Upon Claim Constructions.
value associated with a first condition/value associated with a second condition (claims 14, 24)	a score associated with a normal or abnormal condition/a score associated with the other of a normal or abnormal condition  Joint Submission of Agreed-Upon Claim Constructions.

## '182 Patent (Luck)

Term	Court construction
image (claims 1, 2, 21)	a digital representation
displaying and visual display (claims 1, 3, 4, 21)	presenting information on a computer monitor or screen
resolution (claim 2)	magnification setting on a microscope
	<b>Previously agreed-upon construction</b>

<p>predetermined criteria (claims 1, 21)</p>	<p>standards established before, and then used during, the classification process</p> <p>Joint Submission of Agreed-Upon Claim Constructions.</p>
<p>means for selecting at least one object for display (claim 21)</p>	<p><u>Function</u>: selecting at least one object for display <u>Structure</u>: the processor that selects the objects that have been most highly ranked by the means for classifying objects, and equivalent structures</p> <p>Joint Submission of Agreed-Upon Claim Constructions.</p>
<p>means for displaying at least part of such second image (claim 21)</p>	<p><u>Function</u>: displaying at least part of the second image <u>Structure</u>: a high resolution monitor, and equivalent structures</p> <p>Joint Submission of Agreed-Upon Claim Constructions.</p>
<p>classifying objects (claims 1, 3, 21)</p>	<p>a process or assigning an object into one of two or more groups</p> <p>Markman Hearing Transcript, Day 2 at 3-4.</p>
<p>means for obtaining a first image (claim 21)</p>	<p><u>Function</u>: obtaining a first image <u>Structure</u>: an automated microscope and attached camera, and equivalent structures</p> <p>Markman Hearing Transcript, Day 2 at 54-55.</p>

means for obtaining a second image  (claim 21)	<u>Function:</u> obtaining a second image  <u>Structure:</u> an automated microscope and attached camera, and equivalent structures  Markman Hearing Transcript, Day 2 at 54-55.
means for classifying objects  (claim 21)	<u>Function:</u> classifying objects, including primary and secondary classification  <u>Structure:</u> digital image processor and related computer programs and neurocomputers, template matching algorithms, holographic processors, or other group processing algorithms and equivalent programs or systems  Markman Hearing Transcript, Day 2 at 60-63

## '327 Patent (Wilhelm)

Term	Court construction
suitably or suitable  (claims 1, 5)	The terms serves as a limitation.  <u>Meaning:</u> appropriate for a purpose
machine processing error flags  (claims 1, 3, 5)	a predetermined value that is an indication of whether a machine has examined the specimen properly.
accumulating  (claim 1)	gathering or collecting one or more things.

scan processing error flags (claims 1, 3)	an indication by the system (i.e. an issued flag) that an error has occurred during scan processing
	<b>Previously agreed-upon construction</b>
normal or abnormal (claim 2)	"normal" means that the cells on the slide are benign and "abnormal" means that the cells are malignant and/or potentially malignant (i.e., demonstrating cellular evidence of Human Papillomavirus (HPV) infection or neoplasia)  Markman Hearing Transcript, Day 2 at 64-67.

## '969 Patent (Kamentsky)

Term	Court construction
microscope station (claims 16, 17, 21)	equipment, not including a cell analysis instrument, at which a human operator performs analysis.
cell analysis instrument (claim 21)	a device, not including a microscope station, that performs measurement or analysis of at least one cell feature on a specimen preparation, such as a specimen slide.

means for computing (claim 16)	<p><u>Function:</u> computing to store information about the slide, which is stored by the means for computing, then made accessible to other microscopes</p> <p>Markman Hearing Transcript, Day 3 at 37-38.</p> <p><u>Structure:</u> The personal computer in the decisions support system of a microscope station using Microsoft Windows, the microprocessors with stage precision encoders on each Cytology Lab Pathfinder, the LAN server, and equivalent structures.</p>
location information of interest (claim 16)	areas of the specimen slide that the reviewer has viewed through the microscope optics at a microscope station
means for automatically recording location information of interest (claim 16)	personal computer that is part of a microscope station having an internal clock for automatically recording the location information of the stage (and, consequently, the slide) at regular clock intervals, and equivalent structures.
	<b>Previously agreed-upon construction</b>
terminal for a database (claim 17)	a location at which data can enter a database, leave a database, or enter and leave a database  Joint Submission of Agreed-Upon Claim Constructors.

network of microscope stations (claims 16, 17, 21)	a plurality of microscope stations interconnected by a communications, data exchange and resource sharing system created by linking two or more computers, or computer devices, and establishing standards, or protocols, so that they work together  Markman Hearing Transcript, Day 3 at 36.
operatively linking (claim 16)	connected to perform an action  Markman Hearing Transcript, Day 3 at 36-37.
means for operatively linking (claim 16)	<u>Function:</u> operatively linking microscope stations <u>Structure:</u> PC LAN server and a twisted pair or wires, and equivalent structures  Markman Hearing Transcript, Day 3 at 36-37.
automatically recording (claim 16)	recording without an instruction from the user to record  Markman Hearing Transcript, Day 3 at 65.